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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,485	03/19/2001	Yoshinari Kumagai	BEAR006CIP	1637

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/812,485	KUMAGAI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *3-5,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because the instant application claims the priority of parent application 09/641,034 under 35 U. S. C. 119(e), which is not correct, it should claim the priority under 35 U. S. C. 120 and/or 121.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-11, and integrin binding motif in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the search of all claims including all three motifs can be made without serious burden. This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no serious search burden. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups would require search of subject matter or sequences unnecessary for the examination of the elected claims. For example, if claim 2 were included, it would require additional search of SEQ ID NO:41 and glycosaminoglycan binding motif; if claims 4 and 5 were included, it would require additional search of SEQ ID NOs:42 and 43, and calcium binding motif; if claim 13 were included, it would require additional search on renal phosphate excretion. Therefore, coexamination of each of these inventions would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. The requirement is still deemed proper and is therefore made FINAL.

Claims 3-5 are directed to the sequences of glycosaminoglycan binding motif and calcium binding motif, thus, they are non-elected and withdrawn from consideration. Therefore, claims 1-2, and 6-11 are examined.

Claim Objections

3. Claims 3-5 are objected to because the claim contains non-elected invention.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2 and 6-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12-16 of copending application 09/641034. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 and 6-11 in the instant application disclose a peptide compound enhances bone growth and comprises about 10 to about 50 amino acids in the sequence, wherein each amino acid is D- or L-conformation, the sequence comprises an integrin binding motif, glycosaminoglycan binding motif or calcium binding motif; and a formulation comprising the peptide compound and a carrier. This is obvious in view of claims 1-9 and 12-16 of copending application which disclose a peptide compound has the biological activity of enhancing bone growth, and comprises about 10 to about 50 amino acids in the sequence, wherein each amino acid is D- or L-conformation, the sequence comprises an integrin binding motif, and a formulation comprising the peptide compound and a carrier. Since the claims of the instant application and those of the copending application are directed to a peptide compound having the biological activity of enhancing bone growth and comprising about 10 to about 50 amino acids in the sequence, wherein each amino acid is D- or L-conformation, and the sequence comprises an integrin binding motif. Thus, claims 1-2 and 6-11 in present application, and claims 1-9 and 12-16 of copending application are obvious variations of a peptide compound enhancing bone growth and comprising about 10 to about 50 amino acids in the sequence, wherein each amino acid is D- or L-conformation, and the sequence comprises an integrin binding motif.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng *et al.* (U. S. Patent 5,849,865, December 15, 1998).

Cheng *et al.* teach (Arg-Gly-Asp)-containing peptides such as SEQ ID NOs:79 and 80 which have 11 amino acids and bind to $\alpha 5\beta 1$ receptor (Fig 2A) can be used for treating osteoporosis and enhancing bone formation (column 15, lines 23-27; claims 1 and 2). The reference also teaches the preparation of a pharmaceutical composition comprising a therapeutically effective amount of the polypeptide and a carrier such as saline, and administration of the composition to a subject either as a bolus or infusion over a period of time (column 14, lines 25-35; column 15, line 62-column 16, line 23; claims 7 and 8).

6. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Rowe (WO 99/60017 November 25, 1999).

Rowe teaches a phosphatonin polypeptide (SEQ ID NO:2, 430 amino acids, all L-configuration), which comprises 10-50 amino acids and a RGD domain, is involved in the regulation of phosphate metabolism and bone mineralization (page 1, paragraph 1; page 43, lines 1-3), and the polypeptide can be used to improve the impaired bone formation (page 49,

paragraph 2; claims 1 and 2). The reference also teaches the preparation of a pharmaceutical composition comprising a therapeutically effective amount of the phosphatonin polypeptide and a carrier such as saline, and administration of the composition to patients by parenteral injection (page 60, paragraph 3; Example 7; claims 7 and 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (U. S. Patent 5,015,628) taken with Rowe (WO 99/60017 November 25, 1999).

Reynolds teaches phosphopeptides having 5-30 amino acids can be used for treating dental diseases, bone diseases such as osteoporosis and osteomalacia, and diseases related to malabsorption of mineral (column 1, lines 28-33), and the phosphopeptides in an effective amount can be formulated in a composition (column 8, lines 35-39) as toothpaste (Example 11;

claim 9), mouthwash (Example 17; claim 10), and topical gel (Example 23; claim 11). However, Reynolds does not disclose the composition comprises a peptide compound having integrin binding motif (RGD). Rowe teaches a phosphatonin polypeptide (SEQ ID NO:2, 430 amino acids, all L-configuration), which comprises 10-50 amino acids and a RGD domain, is involved in the regulation of phosphate metabolism and bone mineralization (page 1, paragraph 1; page 43, lines 1-3), and the polypeptide can be used to improve the impaired bone formation (page 49, paragraph 2; claims 1 and 2). Rowe also teaches the preparation of a pharmaceutical composition comprising a therapeutically effective amount of the phosphatonin polypeptide and a carrier such as saline, and administration of the composition to patients by parenteral injection (page 60, paragraph 3; Example 7; claims 7 and 8). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the phosphatonin polypeptide having bone growth enhancing property as taught by Rowe for preparing the composition of toothpaste, mouthwash or oral patch as taught by Reynolds because the use of phosphatonin polypeptide in the composition can promote the bone growth in the application. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

May 1, 2003

Christopher S.F. Low

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